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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, OAKLAND DIVISION

AliveCor, Inc.,

Plaintiff,

vs.

Apple Inc.,

Defendant.

CASE NO. 4:21-cv-03958-JSW

**PLAINTIFF ALIVECOR, INC.'S SUR-
REPLY IN FURTHER OPPOSITION TO
DEFENDANT APPLE INC.'S *DAUBERT*
MOTION TO EXCLUDE THE
TESTIMONY DR. ROOZBEH JAFARI**

Date: December 8, 2023

Time: 9 am

Place: Courtroom 5, 2nd Floor

The Honorable Jeffrey S. White

[REDACTED]

1 In AliveCor’s opposition to Apple’s Motion to Exclude the Testimony of Dr. Roozbeh Jafari
2 (Dkt. 227-3), AliveCor pointed out that Dr. Jafari neither needed nor intended to prove how well
3 SmartRhythm worked when utilizing HRPO-generated heart rates, because AliveCor itself did that
4 work, through a clinical validation often referred to as the “Passman study.” *Id.* at 6. Dr. Jafari cited
5 the Passman study in his materials considered, *see* Dkt. 222-10 Appx. A (Materials Considered) at
6 2, and, as discussed in the opposition brief, thus instead focused his efforts on explaining *why* Apple
7 gating off HRPO had a deleterious effect on SmartRhythm. Dkt 227-3. at 6-7. Dr. Jafari’s opinions
8 were based primarily on his source code review, and the experiments he conducted to confirm those
9 opinions—*i.e.*, the ones Apple seeks to exclude—were meant to *demonstrate* the existence of the
10 degrading phenomena; not act as the basis for his opinion on why and whether watchOS 5 degraded
11 SmartRhythm’s performance. *Id.* at 7-8.

12 Given how badly it misconstrues Dr. Jafari’s opinions and the purpose of his experiments,
13 Apple now tries to argue:

14 And even if Dr. Jafari were permitted to rely on this information [that he cited in
15 his materials considered list], it would not save his opinions. According to the study
16 raised in AliveCor’s Opposition, the “[p]ositive predictive value for [atrial
17 fibrillation] episodes was 39.9%” for atrial fibrillation episodes that lasted over an
18 hour and 29.9% for episodes that lasted over 30 minutes. Ex. 2 (Stultz Rebuttal) ¶¶
58–62 (quoting validation study); *id.* (Stultz Rebuttal Errata) at 1. In other words,
the study upon which AliveCor’s opposition relies shows that SmartRhythm had
accurately detected atrial fibrillation only approximately a third of the time.

19 Dkt. 240-3 at 5. This is an incredibly incorrect representation of the Passman study for two reasons.

20 First, the positive predictive value (“PPV”) findings to which Apple refers do not address
21 the extent to which SmartRhythm accurately detected episodes of atrial fibrillation. PPV instead
22 “answers the question, ‘if I have a positive test, what is the probability that I actually have the
23 disease?’” Thomas F. Monaghan et al., *Foundational Statistical Principles in Medical Research:*
24 *Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value*, MEDICINA
25 (KAUNAS), May 16, 2021, *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8156826>.
26 As Apple’s own technical expert, Dr. Stultz, conceded, PPV is, in essence, a measure of false
27 positives—not whether SmartRhythm accurately identified when Afib actually occurred. Dkt. 222-
28 5 ¶ 85.

Second, PPV values are significantly reduced when an algorithm attempts to measure a condition, like Afib, that has low prevalence in a given population. This is also something Dr. Stultz conceded, noting that, “for a given sensitivity and specificity, the positive predictive value (“PPV”) will be worse in a population with low prevalence, relative to a population with a high prevalence.” Dkt. 222-9 ¶ 94. In the Passman study, the subjects experienced just 1127.1 hours of Afib out of the 31,348.9 hours of data collected from study subjects. Dkt. 227-5 (Passman study) at -858. A lower PPV is, according to Dr. Stultz himself, to be expected with an algorithm designed to detect a rare condition like atrial fibrillation.¹

The true measure of SmartRhythm’s accuracy is not PPV, but *sensitivity*. “Sensitivity, or true positive rate, quantifies how well a test identifies true positives (i.e., how well a test can classify subjects who truly have the condition of interest).” Monaghan et al., *Foundational Statistical Principles in Medical Research: Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value*, MEDICINA (KAUNAS), May 16, 2021. Here, the Passman study authors noted that, out of the 82 episodes of Afib detected by a reference cardiac monitor, SmartRhythm detected 80 of them when the alert threshold was set to one hour. Dkt. 227-5 (Passman study) at -858. This yielded a ***sensitivity rate of 97.5%***—meaning that, contrary to Apple’s claim, SmartRhythm correctly identified ***nearly every instance*** of Afib in study participants. *Id.*; *see also id.* at -864 (reporting a sensitivity of 95.7% when the reporting threshold was decreased to 30 minutes). Apple’s reliance on the study’s PPV findings and its total omission of the corresponding sensitivity findings are highly misleading at best, and flatly wrong at worst.

To reiterate AliveCor’s point from its opposition brief, Dr. Jafari never intended to prove that SmartRhythm worked originally because that evidence will come from AliveCor itself. Apple’s arguments that Dr. Jafari had to thus prove that performance as a statistical matter (including by

¹ SmartRhythm’s PPV in the Passman study is not only expected, but also consistent with AliveCor’s approach in providing continuous monitoring. As AliveCor explained in its Motion for Partial Summary Judgment, Apple itself conceded that consumers might choose continuous heart rhythm analysis—even if that form of monitoring resulted in more false positives than intermittent monitoring—because continuous monitoring could likely detect irregular heart rhythm episodes that intermittent monitoring would miss. Dkt. 193-3 at 12.

essentially running a clinical validation study himself) therefore remains entirely incorrect—and it continues to ignore that Dr. Jafari’s limited experiments were meant to demonstrate a phenomena in action and highlight why the changes he observed in Apple’s watchOS 5 source code would degrade SmartRhythm’s performance. There is no basis to exclude Dr. Jafari’s opinions, and Apple’s continuing mischaracterizations of the record strongly underscore that point.

DATED: September 26, 2023

QUINN EMANUEL URQUHART & SULLIVAN,
LLP

By /s/ Adam Wolfson

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CERTIFICATE OF SERVICE

I, Adam Wolfson, hereby certify that on September 26, 2023, the foregoing **PLAINTIFF ALIVECOR, INC.’S SUR-REPLY IN FURTHER OPPOSITION TO DEFENDANT APPLE INC.’S *DAUBERT* MOTION TO EXCLUDE THE TESTIMONY DR. ROOZBEH JAFARI** was filed with the Clerk of the Court via CM/ECF. Notice of this filing will be sent electronically to all registered parties by operation of the Court’s electronic filing systems.

DATED: September 26, 2023

By /s/ Adam B. Wolfson
Adam B. Wolfson